REMARKS

Claims 10-14, 16-20, 25 and 27-50 were pending in the present application. Claims 1-9, 11, 25, and 33 have been canceled without prejudice. Claim 51 has been added. Thus, claims 10, 12-14, 16-20, 27-32, and 34-51 are pending. To further prosecution without acquiescing to the Examiner's arguments, Applicants have amended independent claim 10. As amended, claim 10 relates to a process for preparing crystallized agglomerates of alkali metal clavulanate salts, comprising stirring the alkali metal clavulanate salt in a solvent and antisolvent mixture. This amendment is supported in the specification and does not include new matter. (See e.g., specification at page 5, lines 21-28. Applicants address the Examiner's rejections in view of the amended claims.

Rejections under 35 U.S.C. § 102

First, claims 37-38, 40-42 and 44-50 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. patents 4,454,069; 6,417,352; and 5,288,861. Although the Office Action also included claim 21 in this rejection, this claim has been previously canceled, rendering the rejection moot as to this claim. Applicants address the Examiner's rejection in view of amended claim 37. As amended, claim 37 relates to an agglomerate of clavulanates obtained by stirring an alkali metal clavulanate salt in a solvent and antisolvent mixture.

U.S. patent 4,454,069 describes potassium clavulanate needles crystallized by adding potassium 2-ethyl hexanoate to a solution or suspension of an amine-clavulanate salt. (See, '069 patent at col. 5, lines 32-39 and Example 4). Similarly, U.S. patent 6,417,352 describes potassium clavulanate needles crystallized by adding potassium-2-ethyl hexanoate to a solution of clavulanic acid. (See, '352 patent at col. 4, lines 40-56). Because the '069 and '352 patents are silent regarding agglomerates obtained by stirring an alkali metal clavulanate salt in a solvent and antisolvent mixture, these patents do not anticipate claims 37-38, 40-42 and 44-51. Furthermore, the needles obtained using the methods in the '069 and '352 patents have greater compressibility compared to the agglomerates of the present invention (see Table 1 in Example 8, "Comparison of agglomerates and needles of potassium clavulanate, optionally mixed with Avicel PH112").

U.S. patent 5,288,861 describes rosette-form crystals obtained by reverse precipitation of potassium clavulanates, by adding a solution of potassium clavulanate to a non-solvent. (See, '861 patent at col. 3, liens 53-57; and at col. 4 lines 18-24). As rosette-like crystalline forms of potassium clavulanate have been excluded in claim 37, this patent does not anticipate claims 37-38, 40-42 and 44-50.

Second, claims 37-50 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by WO 97/33564. WO 97/33564 describes a method for producing auxiliary-free agglomerates of a β-lactam antibiotic, by forming a paste from a β-lactam antibiotic with a liquid, and subsequently kneading and extruding the paste. More particularly, the agglomerates of β-lactam antibiotics disclosed in WO 97/33564 may be mixed with a clavulanate, but the agglomerates themselves do not contain the clavulanate. (See e.g., WO 97/33564 at page 9, lines 1-22; Examples 7-11; and claims 7 and 10). Thus, WO 97/33564 specifically deals with auxiliary-free agglomerates of β-lactam antibiotics which are not clavulanates. Because WO 97/33564 is silent regarding agglomerates obtained by stirring an alkali metal clavulanate salt in a solvent and antisolvent mixture, WO 97/33564 does not anticipate claims 37-50.

Third, claims 10-14, 16-19, 25, 27-32, 37-38 and 42-45 were rejected under 35 U.S.C. § 102(b), as allegedly being anticipated b WO 98/21212. WO 98/21212 describes the crystallization of potassium clavulanates from an amine clavulanate salt by adding a potassium source, preferably potassium ethyl hexanoate. Again, WO 98/21212 fails to teach a process for crystallizing an alkali metal clavulanate salt by stirring an alkali metal clavulanate salt in a solvent and antisolvent mixture. Thus, WO 98/21212 does not anticipate claims 10, 12-14, 16-19, 27-32, 37-38 and 42-45.

Based on the above, Applicants respectfully request that each rejection under 35 U.S.C. § 102(b) discussed above be withdrawn. Furthermore, new claim 51 is not anticipated by the prior art references cited by the Examiner. Specifically, claim 51 is dependent from claim 37 and thus contains all the limitations in claim 37. As previously discussed, claim 37 is not anticipated. Accordingly, claim 51 is also not anticipated.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 31 and 45 were rejected under 35 U.S.C. § 112 second paragraph, as allegedly being indefinite. Claims 31 and 45 have been amended to recite flowability and compressibility in relative terms, as measured using identical procedures. As amended, claims 31 and 45 are definite, and Applicants respectfully request that this rejection be withdrawn.

Rejection under 35 U.S.C. § 112, first paragraph

Claims 10-14, 16-20, 25, 27-32, 35-45 and 47-50 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. The Examiner alleged that the claims do not reasonably provide enablement for other clavulanates. However, the Examiner indicated that the claims are enabling for potassium clavulanate. Applicants must respectfully disagree.

As amended, independent claim 10 is directed to a process for preparing crystallised agglomerates comprising an alkali metal clavulanate salt, and is enabled for at least two reasons. First, the specification provides working examples for crystallizing potassium clavulanates. Second, the absence of a working example for alkali metal clavulanate salts other than potassium clavulanate does not render the invention nonenabled. Specifically, the claims are enabled because the specification describes the invention in such a manner that one skilled in the art will be able to practice the invention without an undue amount of experimentation. (See e.g., Examples 1-9). Thus, claims 10, 12-14, 16-20, 27-32, 35-45 and 47-50 are enabled, and Applicants respectfully request that this rejection be withdrawn.

Furthermore, claims 10-14, 16-20, 25 and 27-50 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner alleged that the removal of a previous limitation of "high water affinity" results in compounds beyond what the specification teaches. (Final Office Action, page 6). Applicants must respectfully disagree and address the Examiner's rejection in view of the amended claims.

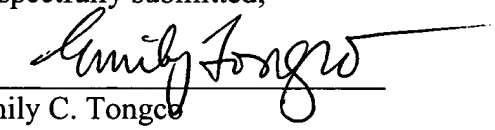
As previously indicated, independent claim 10 is directed to a process for preparing crystallised agglomerates comprising an alkali metal clavulanate salt. Such processes are more than supported in the specification (see e.g., Examples 1-9). Applicants therefore respectfully request that this rejection be withdrawn.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 246152015300. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: March 10, 2004

Respectfully submitted,

By 

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